

# Industry Circular



**Internal Revenue Service**  
Alcohol, Tobacco and Firearms Division  
Washington, D.C. 20224

Industry Circular No. 72-3

FEB 20 1972

## PROPOSED REVOCATION OF AUTHORIZED USE OF DIETHYL PYROCARBONATE

Proprietors of distilled spirits plants,  
bonded wine cellars, breweries,  
and others concerned:

The purpose of this circular is to inform you about a Food and Drug Administration proposed rule making published in the Federal Register of February 11, 1972 (37 F.R. 3060) to withdraw its approval of diethyl pyrocarbonate for use in the production of still wines, beer, noncarbonated soft drinks, and fruit-based beverages. The notice as printed in the Federal Register is reproduced below.

### DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[ 21 CFR Part 121 ]

#### DIETHYL PYROCARBONATE

#### Proposed Revocation of Food Additive Regulation

An order published in the FEDERAL REGISTER of March 23, 1963 (28 F.R. 2900), provided for diethyl pyrocarbonate, manufactured by a specified process, to be added as a fermentation inhibitor to still wines. This regulation was amended (1) by an order published in the FEDERAL REGISTER of June 10, 1964 (29 F.R. 7462), to provide for an alternate method of manufacturing diethyl pyrocarbonate; (2) by an order published in the FEDERAL REGISTER of March 8, 1967 (32 F.R. 3819), to provide for the use of the additive in fermented malt beverages; and (3) by an

order published in the FEDERAL REGISTER of August 30, 1968 (33 F.R. 12229), to provide for the use of the additive in noncarbonated soft drinks and fruit-based beverages.

Recent information has raised questions about the safety of diethyl pyrocarbonate. It has been shown that this ingredient is theoretically capable of combining with other ingredients to form a byproduct that may present a health hazard. Although this possibility has not yet been proved to occur in any marketed product, in view of this information, this ingredient can no longer be regarded as having been shown to be safe as required by section 409 of the Federal Food, Drug, and Cosmetic Act.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 701(a), 52 Stat. 1055, 72 Stat. 1785-88 as amended; 21 U.S.C. 348, 371(a)) and under authority delegated to him (21 CFR 1.120), the Commissioner of Food and Drugs proposes to amend Part 121 by revoking § 121.1117 *Diethyl pyrocarbonate*, on the ground that a fair

evaluation of all the data before him fails to establish that the use of the ingredient is safe.

Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

If suitable data are presented showing that this ingredient may continue to be used safely under the conditions prescribed by the present regulation or under other appropriate conditions, this proposal will be terminated.

Dated: February 8, 1972.

CHARLES C. EDWARDS,  
Commissioner of Food and Drugs.

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Inquiries regarding this circular should refer to its number and be addressed to your Assistant Regional Commissioner, Alcohol, Tobacco and Firearms.

Rex D. Davis, Director  
Alcohol, Tobacco and Firearms Division